

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

JUAN CABRERA,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

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Case No. 07-CIV-9935

DEFENDANT BOSTON SCIENTIFIC CORPORATION'S
ANSWER TO PLAINTIFF'S COMPLAINT

COMES NOW Defendant Boston Scientific Corporation (hereinafter referred to as "BSC") and hereby files this Answer to Plaintiff's Complaint, respectfully showing the Court as follows:

FIRST CAUSE OF ACTION –
DEFECT IN DESIGN

1. BSC also demands a trial by jury on all issues.
2. BSC objects to the allegations contained in Paragraph 2 as calling for a legal conclusion, and therefore denies the same.
3. BSC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 and therefore denies same.
4. BSC admits the allegations contained in Paragraph 4.
5. BSC admits the allegations contained in Paragraph 5.
6. BSC objects to the allegations contained in Paragraph 6 as calling for a legal conclusion. BSC admits that it is a foreign corporation authorized to do business within the State of New York. The remaining allegations contained in Paragraph 6 are denied.

7. BSC objects to the allegations contained in Paragraph 7 as calling for a legal conclusion. BSC admits that it is a foreign corporation authorized to do business within the State of New York. The remaining allegations contained in Paragraph 7 are denied.

8. BSC objects to the allegations contained in Paragraph 8 as vague, ambiguous and calling for a legal conclusion, and therefore denies the same.

9. BSC denies the allegations contained in Paragraph 9.

10. BSC objects to the allegations contained in Paragraph 10 as overbroad, vague and ambiguous as to the term “at all times.” BSC also objects to the term “promoting” as vague and ambiguous. BSC admits that it is engaged in the business of manufacturing, selling, distributing, designing and testing drug eluting stents, including the TAXUS™ Express2™ Paclitaxel-Eluting Coronary Stent System (“TAXUS Stent”). The remaining allegations contained in Paragraph 10 are denied.

11. BSC objects to the allegations contained in Paragraph 11 as vague and ambiguous as the term “substantial benefits” is not defined. BSC admits that it placed drug eluting stents, including the TAXUS Stents, into the stream of commerce. BSC also admits that that TAXUS Stents were sold for profit in the State of New York. The remaining allegations contained in Paragraph 11 are denied.

12. BSC objects to the allegations contained in Paragraph 12 as vague and ambiguous as the terms “persistent courses of conduct” and “substantial revenue” are not defined. BSC admits that it is a foreign corporation authorized to do business within the State of New York. The remaining allegations contained in Paragraph 12 are denied.

13. BSC objects to the allegations contained in Paragraph 13 as vague and ambiguous as the terms “consequences” and “substantial revenue” are not defined. Accordingly, the allegations contained in Paragraph 13 are denied.

14. BSC objects to the terms “promoting” and “held itself out” as vague and ambiguous as the terms are not defined. BSC denies that it made any representations to the Plaintiff herein. The remaining allegations contained in Paragraph 14 are denied.

15. BSC objects to the allegations contained in paragraph 15 as vague and ambiguous as the terms “held itself out” and “standards of such care prevalent within the local, state, and national community” are not defined. BSC denies that it made any representations to the Plaintiff herein. The remaining allegations contained in Paragraph 15 are denied.

16. BSC admits that it is engaged in the business of manufacturing, creating, designing, testing and distributing the TAXUS Stent. BSC objects to the remaining allegations contained in Paragraph 16 as vague and ambiguous. BSC is required to abide by the Food and Drug Administration regulations regarding the labeling, packaging, marketing, advertising and warnings associated with the TAXUS stent. Further, Plaintiff’s allegations contained in Paragraph 16 are vague and ambiguous as the term “sterilize” and “supply” is not defined. The remaining allegations contained in Paragraph 16 are denied.

17. BSC objects to the allegations contained in Paragraph 17 as vague and ambiguous as the term “widely advertised” is not defined. The allegations contained in Paragraph 17 are denied.

18. BSC admits that it is engaged in the business of manufacturing, creating, designing, testing and distributing the TAXUS Stent. The remaining allegations contained in Paragraph 18 are denied.

19. BSC incorporates its response to Paragraph 16 as though fully set forth herein. Answering further, BSC objects to the allegations contained in Paragraph 19 as vague and ambiguous as the term “advertising and promotional activity” referenced by Plaintiff is not defined or identified. BSC is without knowledge or information sufficient to admit or deny whether “said product was implanted into the Plaintiff’s body based upon the belief that the same was safe to use and was unlikely to subject the Plaintiff to any serious danger or injury as a result of the use of the product”, and therefore denies the same. The remaining allegations contained in Paragraph 19 are denied.

20. BSC admits that the TAXUS Stent is sold to hospitals. BSC denies that it sells the TAXUS stent to hospitals or physicians for implantation into any specific patient. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to such person’s medical care providers who are charged with weighing the risks of the procedure with its benefits.

21. BSC admits that the TAXUS Stent is inserted in a coronary artery, inflated with a small balloon and implanted in the artery. BSC further admits that Paclitaxel eluting stents, such as the TAXUS Stent, release the drug Paclitaxel over time. BSC is without information or knowledge as to whether the stent implanted in the Plaintiff was a BSC stent. Accordingly, to the extent Plaintiff’s allegations contained in Paragraph 21 are specific to Plaintiff, they are denied. The remaining allegations contained in Paragraph 21 are denied.

22. BSC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 22 and therefore denies same.

23. BSC objects to the allegations contained in Paragraph 23 as vague and ambiguous as the terms “promoted” and “marketed” are not defined. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to said person’s medical care providers who are charged with weighing the risks of the procedure with its benefits. The remaining allegations contained in Paragraph 23 are denied.

24. BSC admits that it is engaged in the business of designing, manufacturing, testing, assembling, distributing and selling the TAXUS Stent. BSC objects to the remaining allegations contained in Paragraph 24 as vague and ambiguous. BSC is required to abide by the Food and Drug Administration regulations regarding the labeling, warning, product information, and packaging associated with the TAXUS stent. Further, Plaintiff’s allegations contained in Paragraph 24 are vague and ambiguous as the terms “promoting” and “marketing” are not defined. The remaining allegations contained in Paragraph 24 are denied.

25. BSC admits the allegations contained in Paragraph 25, noting Plaintiff’s incorrect spelling of “Paclitaxel”.

26. BSC objects to the allegations contained in Paragraph 26 as vague and ambiguous as the term “promoted” is not defined. The TAXUS Stent is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter. Restenosis is a risk inherent in any stenting procedure. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to such person’s medical care providers who are

charged with weighing the risks of the procedure with its benefits. The allegations contained in Paragraph 26 are denied.

27. BSC denies the allegations contained in Paragraph 27.

28. BSC objects to the allegations contained in Paragraph 28 as vague and ambiguous as the terms “safety equipment” and “proper protection” are not defined. BSC denies the allegations contained in Paragraph 28 of Plaintiff’s Complaint.

29. BSC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 29 and therefore denies same.

30. BSC is without information or knowledge sufficient to admit or deny whether Plaintiff suffered “physical and emotional injuries and severely diminished quality of life and life expectancy” “subsequent to having the TAXUS Stents implanted”, and therefore denies the same. To the extent Plaintiff is alleging in Paragraph 30 that his purported damages were caused by the TAXUS Stent, the allegations contained in Paragraph 30 are denied.

31. BSC denies the allegations contained in Paragraph 31.

32. BSC objects to the allegations contained in Paragraph 32 as calling for a legal conclusion and, therefore, denies the same.

33. BSC denies the allegations contained in Paragraph 33.

34. BSC denies the allegations contained in Paragraph 34.

35. BSC denies the allegations contained in Paragraph 35.

36. BSC denies the allegations contained in Paragraph 36.

37. BSC is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 37 and therefore denies same. To

the extent Plaintiff is alleging that his damages were caused by any actions or inaction of BSC, such allegations are denied.

38. BSC denies the allegations contained in Paragraph 38.

**SECOND CAUSE OF ACTION --
STRICT PRODUCTS LIABILITY FOR A DEFECT IN MANUFACTURE [sic]**

39. BSC realleges and reincorporates its responses to Paragraphs 1 through 38 as if same were set forth herein verbatim.

40. BSC objects to the allegations contained in Paragraph 40 as vague and ambiguous. Answering further, BSC is without knowledge or information sufficient to admit or deny whether Plaintiff reasonably relied upon “the proper function” of the TAXUS Stents. The allegations contained in Paragraph 40 are denied.

41. BSC denies the allegations contained in Paragraph 41.

42. BSC denies the allegations contained in Paragraph 42.

43. BSC objects to the allegations contained in Paragraph 43 as vague and ambiguous as the term “intended uses” is not defined. The TAXUS Stent is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to such person’s medical care providers who are charged with weighing the risks of the procedure with its benefits. The allegations contained in Paragraph 43 are denied.

44. BSC denies the allegations contained in Paragraph 44.

45. BSC denies the allegations contained in Paragraph 45.

46. BSC denies the allegations contained in Paragraph 46.

47. BSC denies the allegations contained in Paragraph 47.

**THIRD CAUSE OF ACTION –
NEGLIGENCE**

48. BSC realleges and reincorporates its responses to Paragraphs 1 through 47 as if same were set forth herein verbatim.

49. BSC denies the allegations contained in Paragraph 49.

50. BSC denies the allegations contained in Paragraph 50.

51. BSC denies the allegations contained in Paragraph 51.

52. BSC denies the allegations contained in Paragraph 52.

53. BSC objects to the allegations contained in Paragraph 53 as vague and ambiguous as the term “intended uses” is not defined. The TAXUS Stent is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to such person’s medical care providers who are charged with weighing the risks of the procedure with its benefits. The allegations contained in Paragraph 53 are denied.

54. BSC denies the allegations contained in Paragraph 54.

55. BSC denies the allegations contained in Paragraph 55.

56. BSC denies the allegations contained in Paragraph 56.

**FOURTH CAUSE OF ACTION –
BREACH OF EXPRESS WARRANTY**

57. BSC realleges and reincorporates its responses to Paragraphs 1 through 56 as if same were set forth herein verbatim.

58. BSC denies the allegations contained in Paragraph 58.

59. BSC denies the allegations contained in Paragraph 59.

60. BSC denies the allegations contained in Paragraph 60.

61. BSC objects to the allegations contained in Paragraph 61 of Plaintiff's

Complaint as calling for a legal conclusion.

62. BSC denies the allegations contained in Paragraph 62.

63. BSC denies the allegations contained in Paragraph 63.

64. BSC denies the allegations contained in Paragraph 64.

**FIFTH CAUSE OF ACTION –
BREACH OF IMPLIED WARRANTY**

65. BSC realleges and reincorporates its responses to Paragraphs 1 through 64

as if same were set forth herein verbatim.

66. BSC objects to the allegations contained in Paragraph 66 as vague and ambiguous as the term "supplying" is not defined. BSC admits that it manufactures the TAXUS Stent. BSC admits that it places TAXUS Stent into the stream of commerce. The remaining allegations contained in Paragraph 66 are denied.

67. BSC denies the allegations contained in Paragraph 67.

68. BSC denies the allegations contained in Paragraph 68.

69. BSC objects to the allegations in Paragraph 69 as calling for a legal conclusion. BSC does not practice medicine, does not recommend or prescribe stents for specific patients and does not place stents within specific patients. The decision of whether a specific patient is a candidate for a coronary stent is a decision left to said person's medical care providers who are charged with weighing the risks of the procedure with its benefits. The remaining allegations contained in Paragraph 69 are denied.

70. BSC denies the allegations contained in Paragraph 70.

71. BSC denies the allegations contained in Paragraph 71.

72. BSC denies the allegations contained in Paragraph 72.

**SIXTH CAUSE OF ACTION –
FRAUDULENT MISREPRESENTATION**

73. BSC realleges and reincorporates its responses to Paragraphs 1 through 72 as if same were set forth herein verbatim.

74. BSC denies the allegations contained in Paragraph 74.

75. BSC denies the allegations contained in Paragraph 75.

76. BSC denies the allegations contained in Paragraph 76.

77. BSC denies the allegations contained in Paragraph 77.

78. BSC denies the allegations contained in Paragraph 78.

79. BSC denies the allegations contained in Paragraph 79.

80. BSC denies the allegations contained in Paragraph 80.

81. BSC denies the allegations contained in Paragraph 81.

**SEVENTH CAUSE OF ACTION –
FRAUDULENT CONCEALMENT WARRANTY [sic]**

82. BSC realleges and reincorporates its responses to Paragraphs 1 through 81 as if same were set forth herein verbatim.

83. BSC denies the allegations contained in Paragraph 83.

84. BSC denies the allegations contained in Paragraph 84.

85. BSC denies the allegations contained in Paragraph 85.

86. BSC objects to the allegations contained in Paragraph 86 as calling for a legal conclusion. To the extent Plaintiff is alleging that the TAXUS Stent is or was defective, any such allegation is denied. BSC denies the allegations contained in Paragraph 86.

87. BSC denies the allegations contained in Paragraph 87.

88. BSC denies the allegations contained in Paragraph 88.

89. BSC denies the allegations contained in Paragraph 89.

90. BSC denies the allegations contained in Paragraph 90.

91. BSC denies the allegations contained in Paragraph 91.

WHEREFORE, BSC prays as follows:

- (a) The Plaintiff takes nothing by way of his Complaint;
- (b) For attorneys fees and costs as permitted by law; and
- (c) Any such further relief as the Court may deem just and proper.

DEFENSES

1. By alleging the defenses set forth below, BSC does not admit that it has the burden of proof and/or burden of persuasion with respect to any of these defenses.

2. Plaintiff's Complaint fails to state a claim upon which relief may be granted.

3. Plaintiff's injuries and damages, if any, were caused by or contributed to by the acts and failures to act of persons or entities other than BSC and for whom BSC cannot be held liable.

4. Plaintiff's injuries, damages and/or losses, if any, were proximately caused by the negligence and/or fault of Plaintiff and BSC is entitled to an allocation of Plaintiff's damages, if any, in accordance with Article 14-A of the New York CPLR.

5. Plaintiffs' claims are barred, in whole or in part, pursuant to 21 U.S.C. § 360k(a), and because Plaintiffs' claims are in conflict with the Food Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated by the United States Food and Drug Administration ("FDA") thereunder. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the, United States Constitution, Article VI, clause 2, and/or the laws of the United States.

6. The Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive damages.

7. Any award of punitive damages in this case would violate the due process clause of the Fourteenth Amendment to the United States Constitution and similar provisions of the Constitution, law and public policy of New York State.

8. The Plaintiff's claims are barred by the "Learned Intermediary" or "Informed Intermediary" doctrine which relieves manufactures from the responsibility to provide certain information directly to patients.

9. To the extent that plaintiff is alleging fraud or similar conduct, plaintiff has failed to plead fraud with sufficient particularity.

10. BSC is entitled to contribution from any person and/or entity whose negligence or other fault contributed to Plaintiff's alleged injuries and damages if Plaintiff receives a verdict against BSC.

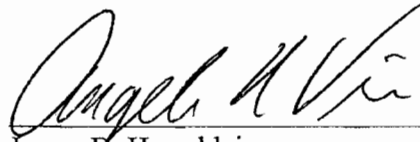
11. Should BSC be held liable to plaintiffs, which liability is specifically denied, BSC would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in plaintiffs' complaint.

12. In the event that plaintiff recovers a verdict or judgment against BSC, then, pursuant to CPLR 4545(c), said verdict or judgment must be reduced by those amounts which have been paid or indemnified or will, with reasonable certainty, be paid or indemnified to plaintiff, in whole or in part, from any collateral source including insurance, social security, workers compensation or employee benefit programs, for the cost of any medical care, dental care, custodial care, or rehabilitation services, or for any loss of earnings or other economic loss.

13. BSC invokes the provisions of Article 50-B of the New York CPLR.

14. BSC specifically reserves the right to amend its Answer, including the assertion of additional affirmative defenses, as discovery and information warrant.

This 11th day of January, 2008.



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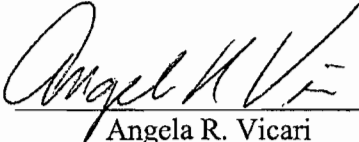
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 11th day January, 2008, the foregoing was served electronically through the CM/ECF system and via First Class U.S. mail, postage prepaid, on the following counsel or parties:

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